REMARKS

Claims 1 through 9, 21 and 22 are pending in this application.

Claims 1, 5-6, 21 and 22 have been amended, and claims 2-4 have been canceled by this amendment.

I. Claim Rejections

Claims 1-3 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Palmirotta et al. ("Origin and Gender Determination of Dried Blood on a Statue of the Virgin Mary" Journal of Forensic Science. March 1998. (43) 2, Pages 431-434).

Claims 1-2, 7, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Carroll et al. ("Large-scale Analysis of the Alu Ya5 and Yb8 Subfamilies and their Contribution to Human Genomic Diversity" Journal of Molecular Biology. 2001. 311, Pages 17-40)

Claim 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Palmirotta et al. or Carroll et al. in view of Hoglund et al. ("Isolation and characterization of radiation hybrids for human chromosome 12" Cytogenetic Cell Genetics. 1995. 69, Pages 240-245).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll et al. in view of Hoglund et al., in further view of Jurka ("A new subfamily of recently retroposed human Alu repeats" Nucleic Acids Research. 1993. Vol. 21. No. 9, Page 2252).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll et al. in view of Hoglund et al., in further view of Batzer et al. ("Standardized Nomenclature for Alu Repeats" Journal of Molecular Evolution. 1996. 42, Pages 3-6).

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmirotta et al. or Carroll et al., in view of Gelmini et al. ("Quantitative polymerase chain reaction-based homogeneous assay with fluorogenic probes to measure c-*erb*B-2 oncogene amplification" Clinical Chemistry. 1997. 43:5, Pages 752-758).

Claim 1 has been amended to incorporate the feature of claim 4, and claims 21 and 22 have been amended to incorporate the feature of "intra-Alu PCR".

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - §2143.03 for decisions pertinent to each of these criteria.

The examiner failed to establish the prima facie case of obviousness because the above three basic criteria are not met.

First, the quantitation step is neither suggested nor taught by Palmirotta et al. or Carroll et al, or in combination with Hoglund et al.

Claims 1, 21 and 22 recite quantitating the human DNA by comparing the amplified DNA with a reference. The quantitation step is not found in Palmirotta et al or Carroll et al. in view of Hoglund et al. The examiner argued that the quantitation step is found in Figure 1 of

Palmirotta et al. Palmirotta et al. merely discloses that Figure 1 shows that the sample is originated from humans or from a non-human catarrhine primate. There is no suggestion or teaching to perform the quantitation step in Palmirotta et al. Also, there is no suggestion of the desirability of adding the quantitation step.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Therefore, claims are not obvious over Palmirotta et al. or Carroll et al. in view of Hoglund et al.

Second, there is no suggestion or motivation to combine reference teachings.

Palmirotta et al. discloses the amplification of Inter-Alu sequence to restrict the range of possible origin of the sample to humans, apes, and Old World monkeys. Carroll et al. discloses that over 99% of the Ya5 and Yb8 Alu family members were restricted to the human genome and absent from orthologous positions within the genomes of several non-human primates. Hoglund teaches the use of a pair of inter-Alu primers, ALU3 and ALU5.

The examiner should provide why the use of the pair of Hoglund is desirable compared with Palmirotta et al. and Carroll et al. The prior art does not suggest the desirability of the combination.

The examiner's reasoning is at most that the references can be combined or modified, or that modifications of the prior art to meet the claimed invention would have been within the ordinary skill of the art.

It should be noted that (1) the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of

the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); and (2) a statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab,* 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000).

Third, even if the combination is made, the combined references do not teach or suggest all the features of "intra-Alu PCR".

Claims 1, 21 and 22 recite intra-Alu PCR: This process of intra-Alu PCR is neither suggested nor taught by Palmirotta et al, Carroll et al, or in combination with Hoglund et al. Palmirotta et al and Hoglund et al disclose inter-Alu PCR concepts (amplification of DNA sequences between adjacent Alu elements). Palmirotta `et al, Carroll et al, or in combination with Hoglund et al. does not suggest or teach the quantitation using intra-Alu PCR (amplification of Alu sequence within Alu elements) recited in claims 1, 21 and 22.

Since the examiner failed to establish a prima facie case of obviousness, withdrawal of the rejection is respectfully requested.

Therefore, claims 1, 21 and 22 are patentable, and their dependent claims 5-9 are also patentable.

2. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll et al. in view of Hoglund et al., in further view of Jurka ("A new subfamily of recently retroposed human Alu repeats" Nucleic Acids Research. 1993. Vol. 21. No. 9, Page 2252).

The examiner failed to establish the prima facie case of obviousness because the above three basic criteria are not met.

In addition to the arguments above for claim 1, the examiner failed to establish a prima facie case of obviousness for the following reasons.

The examiner merely argued that the motivation is 100% local similarity of the instant primers in the sequence provided by Jurka. It is not well understood why 100% local similarity suggests the desirability of the combination or the desirability of the claimed sequences. Jurka merely discloses the consensus sequence of Alu Sb subfamily.

The examiner's reasoning is at most that the references can be combined or modified, or that modifications of the prior art to meet the claimed invention would have been within the ordinary skill of the art.

It should be noted that (1) the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); and (2) a statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d

1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab,* 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000).

Since the examiner failed to establish a prima facie case of obviousness, withdrawal of the rejection is respectfully requested.

3. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmirotta et al. or Carroll et al., in view of Gelmini et al. ("Quantitative polymerase chain reaction-based homogeneous assay with fluorogenic probes to measure c-*erb*B-2 oncogene amplification" Clinical Chemistry. 1997. 43:5, Pages 752-758).

The examiner did not provide the reasoning for claims 7 and 8. Instead, the examiner provided the reasoning for the rejection of claim 9 using TaqMan chemistry.

Claims 7, 8 and 9 depend from claim 1. The applicant explained why claim 1 is patentable.

Therefore, claims 7, 8 and 9 are patentable.

No fees are incurred by this Amendment.

In view of the above, all claims are submitted to be allowable and this application is believed to be in condition to be passed to issue. Reconsideration of the rejections is requested. Should any questions remain unresolved, the Examiner is requested to telephone Applicant's attorney.

Respectfully submitted,

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